UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,426	10/14/2004	Tatsuo Hoshino	21246 US (CO38435/0181394	2404

7590 08/07/2008

Stephen M Haracz
Bryan Cave
1290 Avenue of the Americas
New York, NY 10104

EXAMINER	
MARX, IRENE	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
08/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,426	HOSHINO ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-17 and 19-22* is/are pending in the application.

4a) Of the above claim(s) *1-6,8,9,14,16,17,19 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,10-13,15,21 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 4/29/08 is acknowledged.

Claims 7, 10-13, 15, 21 and 22 are being considered on the merits. Claims 1-6, 8-9, 14, 16-17 and 19-20 are withdrawn from consideration as directed to a non-elected invention.

To clarify the invention it is recommended that in claims 11-12 and 22 the "corresponding" aldose raw material be identified.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 10-13, 15, 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7 and 13 are confusing in that the properties of the enzyme used in the process are substantially similar except that the enzyme specificity is indicated as different. These inconsistent recitations are particularly confusing in the context of claims directed to making any carboxylic acid or its lactone from any aldose with the enzyme(s).

Claim 15 is confusing in the recitation of "is prepared from a cell-free extract, since there are not process steps.

Claims 12 and 22 are substantial duplicates.

Claims 7, 10-13, 15, 21 and 22 are incomplete in the absence of a recovery step for the product produced.

While there is no specific rule or statutory requirement which specifically addresses the need for a recovery step in a process of preparing a composition, it is clear from the record and would be expected from conventional preparation processes that the product must be isolated or recovered. Thus, the claims fail to particularly point out and distinctly claim the "complete" process since the recovery step is missing from the claims. The metes and bounds of the claimed process are therefore not clearly established or delineated.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that one of ordinary skill in the art would have understood the process in the absence of a recovery process. However, the claims as written fail to recite the complete process as there is no agreement between the preamble and the body of the claim. The sole step is "contacting". There is no clear indication of the result of "contacting" other than in the intended purpose of the process. Also note the enzyme specificity variability as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7, 10-13, 15, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asakura *et al.* for the reasons as stated in the last Office action and the further reasons below.

The claims are directed to a process of using purified aldehyde dehydrogenase *Gluconobacter* to produce a carboxylic acid and/or its lactone from an aldehyde, in particular strain *Gluconobacter oxidans DSM* 4025.

Asakura *et al.* disclose the production of carboxylic acid from an aldehyde using a purified aldehyde dehydrogenase from strain *Gluconobacter oxidans DSM* 4025, using the same conditions as claimed. See, e.g., col. 6, lines 14-20.

The reference differs from the claimed invention in that the specific production of vitamin C is not disclosed. However, one of ordinary skill in the art would reasonably have expected at the time the claimed invention was made that the required biotransformation to occur

using the cell extract from this strain, since it has been shown to be capable of the required production of carboxylic acids from aldehydes, and the required reaction is inherent in the identical strain.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Asakura *et al.* by using a cell-free extract of *Gluconobacter oxidans DSM* 4025 to produce vitamin C by adjusting process conditions, if necessary, for the expected benefit of optimizing the production of this useful vitamin.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that the obviousness rejection is improper because the mechanism of the enzymatic process is different and because the molecular weight(s) disclosed are also different. To begin with, the "purified" enzyme used in the claimed process is clearly obtainable from the cell-free extract disclosed by Asakura for the identical strain of *Gluconobacter oxydans* DSM 4025. Secondly, Applicant does not require any particular degree of purification for the enzyme. Thirdly, the enzyme(s) as used in the process has(have) internal differences in substrate specificity as now claim designated.

Applicant indicates that in Asakura one of ordinary skill in the art would understand that to produce vitamin C, a separate step would be necessary to convert the 2-KGA intermediate to vitamin C. Yet, there is nothing in the as claimed invention to require a one step conversion to vitamin C. As a matter of fact, the process as claimed only prepares vitamin C in claim 10. Yet in claim 10 either 2-keto-L-gulonic acid or vitamin C are produced from **L-sorbosone**. Accordingly, the argument that "the claimed process in which an aldose such as **sorbose** can be converted into its lactone such as Vitamin C in a single processing step and by the action of a single enzyme can be viewed as an important milestone for industrial production of Vitamin C", is inconsistent with the invention as claimed.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Therefore, these arguments fail to persuade.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/
Primary Examiner
Art Unit 1651